

EPA Registration #82633-20

Pt. 2

PROCESSING REQUEST

Reg # 82633-20

Decision # 523042 + 525065

Description: CSF Amendments

Electronic Label & Letter
(see PPLS):

OR

Non Electronic
Label & Letter
(Scanning required):

☐ Dated:

☐ Dated:

Only one label type should be selected

Other Materials Sent (see jacket):

☒ New CSF(s) Dated: AH#2
A17#1 6/7/2017 + 12/22/2016

☐ Other:

File this coversheet and attached materials in the jacket. It must be well organized and clipped together, NOT STAPLED. Then give the jacket with the coversheet and materials to staff in the Information Services Center (ISC) (Room S-4900). If a jacket is full or only available as an image, please file materials in a new jacket and bring it down to the (ISC). For further information please call 703-605-0716.

Reviewer: Shanta Adeeb

Division: RD/HB

Phone: 347-0502

Date: 8/14/17



UNITED STATES ENVIRONMENTAL PROTECTION AGENCY
WASHINGTON, DC 20460

OFFICE OF CHEMICAL SAFETY
AND POLLUTION PREVENTION

August 11, 2017

James Wagner
Agent Sharda Cropchem Limited
c/o Wagner Regulatory Associates, Inc.
P.O. Box 640
Hockessin, DE 19707

Subject: PRIA CSF Amendment – Adding Alternate CSF 2
Product Name: Sharda Dicamba Technical
EPA Registration Number: 82633-20
Application Date: December 22, 2016
Decision Number: 525065

Dear Mr. Wagner:

The Confidential Statement of Formula (CSF) referred to above, submitted in connection with registration under the Federal Insecticide, Fungicide and Rodenticide Act, as amended, is acceptable. This approval does not affect any conditions that were previously imposed on this registration. You continue to be subject to existing conditions on your registration and any deadlines connected with them.

Please note that the record for this product currently contains the following CSFs:

- Basic CSF dated 05/23/2014
- Alternate CSF 1 dated 06/07/2017
- Alternate CSF 2 dated 12/22/2016

Any CSFs other than those listed above are superseded/no longer valid. If you have any questions, please contact Shanta Adeeb by phone at 703-347-0502, or via email at adeeb.shanta@epa.gov.

Sincerely,

A handwritten signature in black ink, appearing to read "Kathryn V. Montague".

Kathryn Montague, Product Manager 23
Herbicide Branch
Registration Division (7505P)
Office of Pesticide Programs



FEE

UNITED STATES ENVIRONMENTAL PROTECTION AGENCY
WASHINGTON, D.C. 20460

OFFICE OF CHEMICAL SAFETY AND POLLUTION PREVENTION
OFFICE OF PESTICIDE PROGRAMS REGISTRATION DIVISION (7505P)

DP BARCODE No.: 437825; **FILE SYMBOL No.:** 82633-20 (alt CSF#2); **PRODUCT NAME:** Sharda Dicamba Technical; **DECISION No.:** 525065; **PC Code(s):** 029801; **ACTION CODE:** R351; **FOOD Use:** Yes

DATE: August 2, 2017

SUBJECT: Product Chemistry Review of "Sharda Dicamba Technical"

FROM: Shyam Mathur, Ph. D
Product Chemistry Team Leader
Technical Review Branch/RD (7505P)

Shyam Mathur
8-2-17

TO: Shanta Adeeb / Kathryn Montague, RM 23
Herbicide Branch / RD (7505P)

REGISTRANT: Sharda Worldwide

USE: Herbicide

FOOD USE: Yes [X] No []

MRID Numbers: 50137601 to 50137603

INTRODUCTION:

The registrant has submitted an application to amend the registration of the technical product Sharda Dicamba technical. The amendment involved the submission of an alternate CSF #2 (dated 12-22-2016) and the supporting group A product chemistry data with MRID Nos. 50137601 to 50137603. The proposed alternate CSF# 2 represents the new production site- [REDACTED]. The current CSF's and the corresponding sites are listed below:

Alternate CSF #1 (dated June 7, 2017): [REDACTED]

Current Basic CSF (dated 05-23-2014): [REDACTED]

[REDACTED] as the production site.

CITAB has been asked to evaluate and determine the acceptability of the proposed alternate CSF #2 (dated 12-22-2016) and the supporting product chemistry.

SUMMARY OF FINDINGS:

1. The findings for Group A guideline data were as follows:

830.1550 (product identity & composition): The registrant has submitted an alternate CSF#2 (dated 12-22-2016). The product chemistry data corresponding to this guideline submitted on the CSF satisfy the data requirements of 40CFR§158.320. The nominal concentration 98.61% for AI is within the certified limits of the product label claim nominal concentration (99.1%). The analysis for dioxins & furans shows that all dioxin congeners are below the EPA level of concern of 0.1 ppb and that average levels of all congeners for all five batches are below 0.1 ppb [MRID No. 50137601].

830.1600 (description of materials used to produce the product): The product chemistry data submitted corresponding to this guideline satisfy the data requirements of 40CFR§ 158.325. The registrant has submitted the MSDS's for all the starting materials used to produce the dicamba technical [MRID No. 50137601].

830.1620 (description of production process): The product chemistry data submitted corresponding to this guideline satisfy the data requirements for 40CFR§158.330. The dicamba technical was produced in a [REDACTED] The details of the production process have been provided by the registrant [MRID No. 50137601].

830.1670 (discussion on the formation of impurities): The product chemistry data submitted corresponding to this guideline satisfy the data requirements for 40CFR§158.340. The registrant has listed only [REDACTED] impurity which was identified and detected at the concentration of >0.1% in addition to [REDACTED]. The registrant has provided the mechanisms of the formation of potential impurities in dicamba technical. The impurities of tox concern like polychlorinated dioxins & furans are present at levels of below 0.1 ppb as determined during the additional 5 batch analysis [MRID No. 50137602].

830.1700 (preliminary analysis): The product chemistry data submitted corresponding to this guideline to support the claims on the CSF satisfy the data requirements of 40CFR§158.345. The five lots of the test substance were analyzed to verify the concentration of Dicamba technical. The AI content and impurities were determined by HPLC-UV method. External standard quantitation method was used to quantify the levels of associated impurities and dicamba. The methodology for the dioxin and furan analysis is based upon US EPA Method 1613 Revision B. with modifications to the method dictated by the matrix, SAL MSOP-1 (version 1.6) includes the SAL modified version of the US EPA method. This method employs isotope dilution/internal standard high resolution gas chromatography – high resolution mass spectrometry as the means of determination. The analysis is performed utilizing authentic labelled and native PCDD/F's as calibration, internal and recovery standards. The objective is to achieve a limit of detection of 0.01 ng/g or better for individual congeners. Details of the validated analytical method have been provided [MRID No. 50137602 & 50137603].

830.1750 (certified limits): The product chemistry data submitted corresponding to this guideline satisfy the requirements of 40CFR§158.350. The nominal concentrations and the certified limits for the active ingredient and the impurities are based on the five batch analysis [MRID No. 50137601].

830.1800 (enforcement analytical method): The product chemistry data submitted corresponding to this guideline satisfy the requirements of 40CFR§158.355. The content of the active ingredient was determined by using Reversed phase HPLC-UV (280 nm) external standard technique. The analytical method was validated for precision, accuracy and linearity [MRID No. 50137603].

Manufacturing process information may be entitled to confidential treatment

DP BARCODE No.: 437825; **FILE SYMBOL No.:** 82633-20 (alt CSF#2); **PRODUCT NAME:** Sharda Dicamba Technical; **DECISION No.:** 525065; **PC Code(s):** 029801; **ACTION CODE:** R351; **FOOD Use:** Yes

CONCLUSIONS:

The CITAB has reviewed the product chemistry data submitted in support of the proposed alternate CSF #2 for Dicamba Technical [REDACTED] and has concluded that:

1. The product chemistry data submitted for guideline 830 Series group A are acceptable.
2. The proposed alternate CSF #2 (dated 12-22-2016) is acceptable. The nominal concentration of 98.6% is within the certified limits of the product label claim nominal concentration of 99.1%.
3. The range of dioxin congeners were determined by using "US EPA Method 1613 Tetra-through Octa-chlorinated Dioxins and Furans by isotope Dilution HRGC/HRMS". The results of this analysis showed that levels of dioxin congeners are well below level of concern of 0.1 ppb. It was also concluded that the average Total TEQ of 5 batches is 0.00001 ng/g. The data submitted are substantially similar to the basic CSF and are acceptable.

Product ingredient source information may be entitled to confidential treatment

DP BARCODE No.: 437825; FILE SYMBOL No.: 82633-20 (alt CSF#2); PRODUCT NAME: Sharda
Dicamba Technical; DECISION No.: 525065; PC Code(s): 029801; ACTION CODE: R351; FOOD Use:
Yes

830.1550. Product identity & composition: (MRID No. 50137601)

Common Name: Dicamba

Chemical Name: 3,6-dichloro-2-methoxybenzoic acid

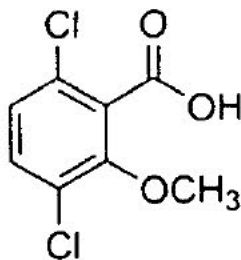
Chemical Name (IUPAC): 3,6-dichloro-o-anisic acid

CAS Number: 1918-00-9

Declared Concentration: 97.32% (nominal)

Molecular Formula: $C_8H_6Cl_2O_3$

Molecular Weight: 221.04 g/mol



Molecular Structure:

Manufacturing site:



Product ingredient source information may be entitled to confidential treatment

DP BARCODE No.: 437825; **FILE SYMBOL No.:** 82633-20 (alt CSF#2); **PRODUCT NAME:** Sharda Dicamba Technical; **DECISION No.:** 525065; **PC Code(s):** 029801; **ACTION CODE:** R351; **FOOD Use:** Yes

Group A Data

Table 1. Manufacturing and Impurity Data Sharda Dicamba Technical (altCSF#2)				
GLN	Requirement	MRID	Status	Details and /or Deficiency
830.1550	Product Identity and composition	50137601	A	See summary of findings
830.1600	Description of materials used to produce the product	50137601	A	See summary of findings
830.1620	Description of production process	50137601	A	See summary of findings
830.1670	Discussion of formation of impurities	50137601	A	See summary of findings
830.1700	Preliminary analysis	50137603 50137602	A	See summary of findings
830.1750	Certified limits	50137601	A	See summary of findings
830.1800	Enforcement analytical method	50137603	A	See summary of findings
A = Acceptable; N = Unacceptable (see Deficiency); N/A = Not Applicable; G = Data gap; I = In progress; U = Up-grade (additional information required);				

DP BARCODE No.: 437825; **FILE SYMBOL No.:** 82633-20 (alt CSF#2); **PRODUCT NAME:** Sharda
Dicamba Technical; **DECISION No.:** 525065; **PC Code(s):** 029801; **ACTION CODE:** R351; **FOOD Use:**
Yes

CONFIDENTIAL APPENDIX



Manufacturing process information may be entitled to confidential treatment



UNITED STATES ENVIRONMENTAL PROTECTION AGENCY
WASHINGTON, DC 20460

OFFICE OF CHEMICAL SAFETY
AND POLLUTION PREVENTION

June 16, 2017

Anna Armstrong
Agent for Sharda Cropchem, Ltd.
Sharda Cropchem, Ltd.
c/o Wagner Regulatory Associates, Inc.
P.O. Box 640 Hockessin, DE 19707

Subject: PRIA CSF Amendment – Add and Alternate CSF 1
Product Name: Sharda Dicamba Herbicide
EPA Registration Number: 82633-20
Application Date: October 28, 2016
Decision Number: 523042

Dear Ms. Armstrong:

The Confidential Statement of Formula (CSF) referred to above, submitted in connection with registration under the Federal Insecticide, Fungicide and Rodenticide Act, as amended, is acceptable. This approval does not affect any conditions that were previously imposed on this registration. You continue to be subject to existing conditions on your registration and any deadlines connected with them.

Please note that the record for this product currently contains the following CSFs:

- Basic CSF dated 05/23/2014
- Alternate CSF 1 dated 06/07/2017

Any CSFs other than those listed above are superseded/no longer valid. If you have any questions, please contact Shanta Adeeb by phone at 703-347-0502, or via email at adeeb.shanta@epa.gov.

Sincerely,

A handwritten signature in black ink, reading "Kathryn V. Montague".

Kathryn Montague, Product Manager 23
Herbicide Branch
Registration Division (7505P)
Office of Pesticide Programs



FEE

UNITED STATES ENVIRONMENTAL PROTECTION AGENCY
WASHINGTON, D.C. 20460

OFFICE OF CHEMICAL SAFETY AND POLLUTION PREVENTION
OFFICE OF PESTICIDE PROGRAMS REGISTRATION DIVISION (7505P)

DP BARCODE No.: 436823; FILE SYMBOL No.: 82633-20 (alt CSF1); PRODUCT NAME: Sharda
Dicamba Technical; DECISION No.: 523042; PC Code(s): 029801; ACTION CODE: R351; FOOD Use:
Yes

DATE: June 8, 2017

SUBJECT: Product Chemistry Review of "Sharda Dicamba Technical"

FROM: Shyam Mathur, Ph. D
Product Chemistry Team Leader
Technical Review Branch/RD (7505P)

TO: Kathryn Montague, RM 23
Herbicide Branch / RD (7505P)

SB Mathur
P. Shah 6/8/17
6/13/2017

REGISTRANT: Sharda Worldwide
USE: Herbicide
FOOD USE: Yes [X] No []
MRID Numbers: 50094101 to 50094105

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INTRODUCTION:

The registrant has submitted an application to amend the registration of the technical product Sharda Dicamba technical. The amendment involved the submission of an alternate CSF #1 (dated 10-28-2016) and the supporting group A product chemistry data with MRID Nos. 50094101 to -05. The proposed alternate CSF# 1 represents the new production site- [REDACTED]. On the advice of the Agency, the registrant submitted the revised alternate CSF #1 dated June 7, 2017 which will supersede the previously submitted altCSF#1 (dated 10-28-2016). The current basic CSF (dated 05-23-2014) indicates [REDACTED] as the production site.

CITAB has been asked to evaluate and determine the acceptability of the proposed revised alternate CSF #1 (dated 06-07-2017) and the supporting product chemistry.

SUMMARY OF FINDINGS:

1. The findings for Group A guideline data were as follows:

830.1550 (product identity & composition): The registrant has submitted a revised alternate CSF#1 (dated 06-07-2017). The product chemistry data corresponding to this guideline submitted on the CSF satisfy the data requirements of 40CFR§158.320. The nominal concentration 97.32% for AI is within the certified limits of the product label claim nominal concentration (99.1%). The analysis for dioxins & furans shows that all dioxin congeners are below the EPA level of concern of 0.1 ppb and that average levels of all congeners for all five batches are below 0.1 ppb [MRID 50094101].

830.1600 (description of materials used to produce the product): The product chemistry data submitted corresponding to this guideline satisfy the data requirements of 40CFR§ 158.325. The registrant has submitted the MSDS's for all the starting materials used to produce the dicamba technical [MRID No. 50094101].

830.1620 (description of production process): The product chemistry data submitted corresponding to this guideline satisfy the data requirements for 40CFR§158.330. The dicamba technical was produced in a [REDACTED]. The details of the production process have been provided by the registrant [MRID No. 50094101].

830.1670 (discussion on the formation of impurities): The product chemistry data submitted corresponding to this guideline satisfy the data requirements for 40CFR§158.340. The registrant has listed only [REDACTED] impurities which were identified and detected at the concentration of >0.1% in addition to [REDACTED]. The registrant has provided the mechanisms of the formation of potential impurities in dicamba technical. The impurities of tox concern like polychlorinated dioxins & furans are present at levels of below 0.1 ppb as determined during the additional 5 batch analysis [MRID No. 50094101 & 50094104].

Product ingredient source information may be entitled to confidential treatment

Manufacturing process information may be entitled to confidential treatment

DP BARCODE No.: 436823; **FILE SYMBOL No.:** 82633-20 (alt CSF1); **PRODUCT NAME:** Sharda
Dicamba Technical; **DECISION No.:** 523042; **PC Code(s):** 029801; **ACTION CODE:** R351; **FOOD Use:**
Yes

- 830.1700 (preliminary analysis): The product chemistry data submitted corresponding to this guideline to support the claims on the CSF satisfy the data requirements of 40CFR§158.345. The five lots of the test substance were analyzed to verify the concentration of Dicamba technical. The AI content and impurities were determined by HPLC-UV method. The GC-MS in SIM mode method was used for the determination of dioxin in technical Dicamba. The analytical methods have been validated for linearity, accuracy and precision. The range of dioxin congeners were also determined by using "US EPA Method 1613 Tetra-through Octa-chlorinated Dioxins and Furans by isotope Dilution HRGC/HRMS". The results of this analysis showed that levels of 7 dioxin congeners in this batch are well below level of concern of 0.1 ppb. It was also concluded that the average Total TEQ of 5 batches is 0.02 ppb, well below 0.1 ppb [MRID No. 50094102 & 50094104].
- 830.1750 (certified limits): The product chemistry data submitted corresponding to this guideline satisfy the requirements of 40CFR§158.350. The nominal concentrations and the certified limits for the active ingredient and the impurities are based on the five batch analysis [MRID No. 50094102].
- 830.1800 (enforcement analytical method): The product chemistry data submitted corresponding to this guideline satisfy the requirements of 40CFR§158.355. The content of the active ingredient was determined by using Reversed phase HPLC-UV (238 nm) internal standard technique. The analytical method was validated for precision, accuracy and linearity. [MRID No. 50094102].
2. The additional data cited & waiver requests submitted for 830 series group B guideline data (physical-Chemical properties) satisfy the data requirements of 40CFR§158.310(e). The registrant has requested waivers with justifications for some of the physical-chemical properties data. The results for one-year storage stability (830.6317) and corrosion characteristics (830.6320) studies are still pending [MRID No. 50094105].

CONCLUSIONS:

The CITAB has reviewed the product chemistry data submitted in support of the proposed revised alternate CSF #1 for Dicamba Technical (produced by [REDACTED])

1. The product chemistry data submitted for guideline 830 Series group A are acceptable.
2. The proposed revised alternate CSF #1 (dated 06-07-2017) is acceptable. The nominal concentration of 99.32% is within the certified limits of the product label claim nominal concentration of 99.1%.
3. The data cited for few of the physical-chemical characteristics are acceptable. Based on the justifications provided, the Agency has no objections in accepting the waiver requests for some of group B product chemistry data. The registrant must submit to the Agency the results of the studies for the guidelines 830.6317 and 830.6320 on completion.
4. The range of dioxin congeners were determined by using "US EPA Method 1613 Tetra-through Octa-chlorinated Dioxins and Furans by isotope Dilution HRGC/HRMS". The results of this analysis showed that levels of dioxin congeners are well below level of concern of 0.1 ppb. It was also concluded that the average Total TEQ of 5 batches is 0.00001 ng/g. The data submitted are substantially similar to the basic CSF and are acceptable.

Product ingredient source information may be entitled to confidential treatment

DP BARCODE No.: 436823; **FILE SYMBOL No.:** 82633-20 (alt CSF1); **PRODUCT NAME:** Sharda
Dicamba Technical; **DECISION No.:** 523042; **PC Code(s):** 029801; **ACTION CODE:** R351; **FOOD Use:**
Yes

830.1550. Product identity & composition: (MRID No. 50094101)

Common Name: Dicamba

Chemical Name: 3,6-dichloro-2-methoxybenzoic acid

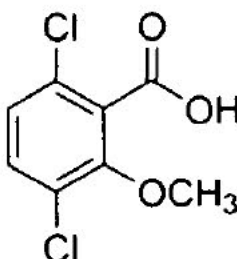
Chemical Name (IUPAC): 3,6-dichloro-o-anisic acid

CAS Number: 1918-00-9

Declared Concentration: 97.32% (nominal)

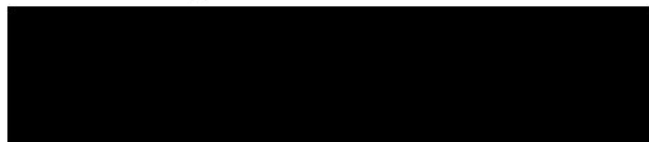
Molecular Formula: $C_8H_6Cl_2O_3$

Molecular Weight: 221.04 g/mol



Molecular Structure:

Manufacturing site:



Product ingredient source information may be entitled to confidential treatment

DP BARCODE No.: 436823, FILE SYMBOL No.: 82633-20 (alt CSF1); PRODUCT NAME: Sharda
Dicamba Technical; DECISION No.: 523042; PC Code(s): 029801; ACTION CODE: R351; FOOD Use:
Yes

Group A Data

Table 1. Manufacturing and Impurity Data Sharda Dicamba Technical (altCSF#1)				
GLN	Requirement	MRID	Status	Details and /or Deficiency
830.1550	Product Identity and composition	50094101	A	Submitted revised altCSF#1 (dated 06-07-17) with NC of 99.32% for the AI which is within the certified limits of the product label claim nominal concentration of 99.10%.
830.1600	Description of materials used to produce the product	50094101	A	Submitted the MSDS's for all the starting materials used in the synthesis of Dicamba technical at the site located at [REDACTED]
830.1620	Description of production process	50094101	A	The Dicamba technical was produced in [REDACTED]. The manufacturing process has been described in detail. The quality assurance procedures adopted in each step of the process have been included.
830.1670	Discussion of formation of impurities	50094101	A	Impurities discussed and identified. The discussions on the mechanisms of the formation of all impurities listed on the CSF have been provided. [REDACTED] impurities have been listed in the CSF which are present at the concentrations of > 01.%. The registrant has listed polychlorinated dioxins & furans which are present at the concentrations below the 0.1 ppb
830.1700	Preliminary analysis	50094102 To 50094104	A	HPLC/UV (238 nm for AI & 280 nm for impurities) method with internal standard calibration was used for the identification & quantification of the AI and the impurities. PCDD & PCDF analyses were performed by HRGC/HRMS on an Agilent 6890 GC using an Agilent 7683B series auto-sampler coupled to Micromass Auto spec High resolution MS. Both analytes and internal standards were determined by operating the HRGC/HRMS in a selected-ion monitoring (SIM) mode. Details of the method have been submitted
830.1750	Certified limits	50094101	A	The proposed limits for the AI and the impurities are based on five batch analysis.
830.1800	Enforcement analytical method	50094101	A	The HPLC/UV (238 nm) method was used for the determination of the AI contents. The internal standard qualification technique was used. The method was validated for precision, linearity and accuracy.
A = Acceptable; N = Unacceptable (see Deficiency); N/A = Not Applicable; G = Data gap; I = In progress; U = Up-grade (additional information required);				

Manufacturing process information may be entitled to confidential treatment

DP BARCODE No.: 436823; FILE SYMBOL No.: 82633-20 (alt CSF1); PRODUCT NAME: Sharda
 Dicamba Technical; DECISION No.: 523042; PC Code(s): 029801; ACTION CODE: R351; FOOD Use:
 Yes

830 Series Subgroup B (Physical-Chemical properties)

Table 2: Physical and Chemical Properties of : Sharda Dicamba TGA/MUP (basic CSF data)				
GLN	Requirement	MRID	Status	Result or Deficiency
830.6302	Color	490851-04	A	Yellow
830.6303	Physical state	" " "	A	Solid (dry powder)
830.6304	Odor	" " "	A	Characteristic odor
830.6313	Stability to normal and elevated temperatures, metals, and metal ions	490851-05 490851-06	A	Stable at room temperature and also for 2 weeks at 54°C. Stable to metals like stainless steel, Al, Cu, Fe and Brass.
830.6314	Oxidation/reduction: chemical incompatibility	50094105 (New)	A	Waiver request. The chemical structure of the AI indicates that it is not a strong oxidizing or reducing agent
830.6315	Flammability	Waiver request letter 03-19-13	W	Accepted
830.6316	Explosibility	" " "	W	Accepted
830.6317	Storage stability		G	No data submitted
830.6319	Miscibility	Waiver request letter 03-19-13	W	Accepted
830.6320	Corrosion characteristics		G	No data submitted
830.7000	pH	490851-08	A	2.11 (1% m/V) at 20.2°C
830.7050	UV/Visible absorption	475047-09 (Cited)	A	See table below
830.7100	Viscosity	Waiver request letter 03-19-13	W	Accepted
830.7200	Melting point	letter 03-19-13 (cited)	A	115°C [CRC Handbook of Chem. & Phy. 88 th ED. 2007-2008, Boca Raton, FL, p.3-156].
830.7220	Boiling point	Waiver request letter 03-19-13	W	Accepted
830.7300	Density	490851-09	A	Tap = 0.898 g/ml at 25°C Pour = 0.728 g/cc at 25°C
830.7370	Dissociation constants in water (DC)	490851-10	A	pKa = 1.95 & K _a = 1.12 x 10 ⁻² at 25°C using 0.1 mol L ⁻¹ HCl as titrant solution
830.7550	Partition coefficient	490851-11	A	Log P _{ow} = 2.465 at 20°C; pH = 1.47
830.7840	Water solubility:	490851-12	A	Water = 5.393 g/l; acetone = 799.2639 g/l; methanol = 815.3960 g/l @ 20°C
830.7950	Vapor pressure	Letter dated 03-19-13 (cited)	A	3.38 x 10 ⁻⁵ mm Hg at 25°C Refer: SRC PhysProp Data base

DP BARCODE No.: 436823; FILE SYMBOL No.: 82633-20 (alt CSF1); PRODUCT NAME: Sharda
Dicamba Technical; DECISION No.: 523042; PC Code(s): 029801; ACTION CODE: R351; FOOD Use:
Yes

A = Acceptable; N = unacceptable (see Deficiency); N/A = Not Applicable; G = Data gap; I = In progress or need upgrade; U = Upgrade (additional information required)

Note1, 830.7050 (UV-VIS): (MRID No. 475047-09)

A. Ultraviolet and Visible Spectrum

Instrument: Perkin-Elmer Lambda 5 UV/VIS spectrometer
Concentrations: 1.81×10^{-3} M and 3.62×10^{-5} M
Solvent: H₂O (distilled)
Scanning: 200-750 nm, 1 cm cell
Spectrum: see appendix 1

Wavelength (nm)	Molar Absorptivity (L/mol-cm)	Transition
203.1	3.42×10^4	${}^1B \leftarrow {}^1A$
230 (shoulder)	8.68×10^3 (estimate)	${}^1L_a \leftarrow {}^1A$
276.0	5.12×10^2	${}^1L_b \leftarrow {}^1A$
280 (shoulder)	5.03×10^2 (estimate)	${}^1L_b \leftarrow {}^1A$

DP BARCODE No.: 436823; FILE SYMBOL No.: 82633-20 (alt CSF1); PRODUCT NAME: Sharda
Dicamba Technical; DECISION No.: 523042; PC Code(s): 029801; ACTION CODE: R351; FOOD Use:
Yes

CONFIDENTIAL APPENDIX





UNITED STATES ENVIRONMENTAL PROTECTION AGENCY
WASHINGTON, D.C. 20460

OFFICE OF CHEMICAL SAFETY
AND POLLUTION PREVENTION
OFFICE OF PESTICIDE PROGRAMS
REGISTRATION DIVISION (7505P)

May 19, 2017

MEMORANDUM:

Subject: Name of Pesticide Product: SHARDA DICAMBA RECHNICAL
EPA Reg. No. /File Symbol: 82633-20
DP Barcode: DP 437824
Decision No.: 525065
Action Code: R351
Submission: #996779
E-Sub: 16335
PC Code: 029801 (Dicamba: 99.1%)

From: Byron T. Backus, Ph.D., Toxicologist
CITAB
Registration Division (7505P)

Byron T. Backus
May-19-2017

Through: P.V. Shah, Ph.D., Branch Chief
CITAB
Registration Division (7505P)

P.V. Shah
5/22/2017

To: Shanta Adeeb / Kathryn Montague, RM 23
Herbicide Branch
Registration Division (7505P)

Registrant: SHARDA CROPCHEM LIMITED

FORMULATION FROM PROPOSED LABEL:

<u>Active Ingredient(s):</u>	<u>by wt.</u>
029801 Dicamba (3,6-dichloro- <u>o</u> -anisic acid)	99.1%
<u>Other Ingredients:</u>	0.9%
TOTAL	100.0%

ACTION REQUESTED: "Please review the acute tox data for this product. Th registrant has a new unregistered source for Dicamba. Attached are the bean sheet and Alternate CSF 2 for

review. Under e-submission 16335 the cover letter, data transmittal document, data matrix and other administrative documents can be found.

BACKGROUND: The material available to CITAB includes a cover letter (dated December 22, 2016), a data matrix (dated December 22, 2016) and a CSF for alternate # 2 (dated December 22, 2016). From the data matrix the registrant is citing MRIDs 490851-13 through -18 to satisfy the acute toxicity data requirements.

COMMENTS AND RECOMMENDATIONS:

1. The six acute toxicity studies in MRIDs 490851-13 through -18 have been previously reviewed and classified as acceptable (TRB memorandum for 82633-EN dated January 10, 2014).
2. After comparing the proposed alternate #2 CSF with the basic CSF (dated May 23, 2014) for 82633-20 CITAB concludes that these are toxicologically similar formulations. The citations to MRIDs 490851-13 through -18 satisfy the acute toxicity data requirements for acceptance of alternate CSF #2 for 82633-20.
3. The proposed alternate #2 CSF for 82633-20 is toxicologically acceptable.
4. No changes are recommended in the precautionary labeling or first aid statements for 82633-20.



UNITED STATES ENVIRONMENTAL PROTECTION AGENCY
WASHINGTON, D.C. 20460
OFFICE OF CHEMICAL SAFETY AND POLLUTION PREVENTION
OFFICE OF PESTICIDE PROGRAMS REGISTRATION DIVISION (7505P)

DP BARCODE No.: D437825 FILE SYMBOL No.: 82633-20 (screen) DECISION No.: 525065
PC Code: 029801 Company Name: Sharda Cropchem, Ltd.
FOOD Use: No ACTION CODE: R 351 PRODUCT NAME: Sharda Dicamba Technical

DATE OUT: March 27, 2017

SUBJECT: Completeness Check Screen for Manufacturing Use Product

Product Name: Sharda Dicamba Technical

FROM: Bruce Kitchens, Chemist
Product Chemistry Team
Chemistry, Inerts and Toxicology Assessment Branch/RD (7505P)

Bruce Kitchens
3/27/17

TO: RM #23, Kathryn V. Montague/Shanta Adeeb
Herbicide Branch
Registration Division (7505P)

Company Name: Sharda Cropchem, Limited

Active Ingredient: Dicamba (99.1% a.i.)

MRID Nos.: 501376-01, 501376-02 & 501376-03

CONCLUSION:

Deficiencies: Yes

(If there are deficiencies they are indicated below each heading as Note 1, Note 2 Etc).

Group A: All required data submitted

Group B: Not required

CSF: Alternate CSF #2 dated 22 Dec 2016

Product label: See Documentum

Note 1. The proposed alternate CSF #2 dated 22 Dec 2016 requires revision. The CSF states that there are five pages; however, only four pages were submitted.

Note to PM: If the deficiencies are found in the screen results, please inform the registrant and return to me the corrected deficiencies in response to 10-day letter, so that it can be attached to the original bean, if the data package is still in CITAB. New Bean is required in case the bean has been closed by CITAB. Thank you.

Memorandum E-SUBMISSIONDate: 1 / 25 / 17To: PM 23, Regulatory Manager

From: Information Services Branch, ITRMD

Your receipt of this data submission is not an indication that MRIDs for the enclosed studies have been posted to OPPIN.

We expect that it will be approximately 5 days from the above date before the study-level data is available in OPPIN.

If you have any questions about this process, please contact Teresa Downs (305-5363).

This is a: ☒ fully accepted submission
☐ partially accepted submission
☐ rejected submission



UNITED STATES ENVIRONMENTAL PROTECTION AGENCY
WASHINGTON, D.C. 20460

January 19, 2017

OFFICE OF CHEMICAL SAFETY
AND POLLUTION PREVENTION

WAGNER REGULATORY ASSOCIATES, INC.
SHARDA CROP CHEM LIMITED
7217 LANCASTER PIKE, SUITE A
PO.BOX : 640
HOCKESSIN, DE 19707

Report of Analysis for Compliance with PR Notice 11-03

Thank you for your submittal of 22-DEC-16. Our staff has completed a preliminary analysis of the material. The results are provided as follows:

Your submittal was found to be in full compliance with the standards for submission of data contained in PR Notice 11-03. A copy of your bibliography is enclosed, annotated with Master Record ID's (MRIDs) assigned to each document submitted. Please use these numbers in all future references to these documents. Thank you for your cooperation. If you have any questions concerning this data submission, please raise them with the cognizant Product Manager, to whom the data have been released.

DATA TRANSMITTAL DOCUMENT**1. Name and Address of Submitter**

Sharda Cropchem Ltd.
c/o Wagner Regulatory Associates
7217 Lancaster Pike, Suite A, PO Box 640
Hockessin, DE 19707

2. Regulatory Action In Support Of Which This Package Is Submitted

Sharda Dicamba Technical - PRIA R351: Application for CSF Amendment – add new unregistered source of Dicamba active ingredient

3. Transmittal Date

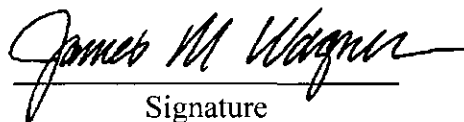
December 22, 2016

4. List of Submitted Studies

50137601	Sharda Dicamba Technical- Product Identity and Composition, Description of Materials, Description of Production Process, Discussion of Formation and Toxicity of Impurities, Preliminary Analysis, and Certified Limits; OPPTS Guidelines: 830.1550, 830.1600, 830.1620, 830.1670, 830.1750
50137602	The Analysis of Polychlorinated Dioxins and Furans in Five Batches of Dicamba, (CAS No: 1918-00-9), Study No. 137, OPPTS Guideline: 830.1670
50137603	Five Batch Analysis of Dicamba Technical, Study No. 5802, OPPTS Guidelines: 830.1700, 830.1800

Company Official:

James Wagner
Authorized Agent


Signature

Company Name: Sharda Cropchem Ltd.

Company Contact:

James Wagner
Authorized Agent

(302) 635-7290
Phone



Wagner Regulatory Associates, Inc.
P.O. Box 640
7217 Lancaster Pike, Suite A
Hockessin, Delaware 19707

Submitted Electronically

December 22, 2016

Document Processing Desk (REGFEE)
ATTN: Kathryn Montague PM 23
Registration Division (7505P)
U.S. Environmental Protection Agency
Office of Pesticide Programs
One Potomac Yard
2777 South Crystal Drive
Arlington, Virginia 22202

Dear Ms. Montague,

**Subject: Sharda Dicamba Technical – EPA Registration No. 82633-20 – amendment
to add a new unregistered source of active ingredient (PRIA R351)**

Wagner Regulatory Associates, Inc., as agent for Sharda Cropchem Ltd., respectfully submits this application to add a new unregistered source of Dicamba active ingredient for the subject product. In support of this request, the following documents have been uploaded to the CDX portal with this submission:

- Letter from Sharda Cropchem, Ltd, appointing Wagner Regulatory Associates, Inc. as its agent
- Application for Pesticide Amendment (8570-1)
- Alternate Confidential Statement of Formula (8570-4)
- Certification with Respect to Citation of Data (8570-34)
- Data Transmittal document
- Data Matrix (internal and public)
- Submission of Studies as reflected in the data transmittal document
- PRIA fee receipt reflecting payment in the amount of \$13,226 for R351

If you have any questions about this submission, please contact the undersigned at (302) 635-7290 or james@wagnerreg.com.

Respectfully submitted,

James Wagner
Agent for Sharda Cropchem, Ltd.

Enclosures

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c/o Wagner Regulatory Associates
7217 Lancaster Pike, Suite A, PO Box 640
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Sharda Dicamba Technical - PRIA R351: Application for CSF Amendment – add new unregistered source of Dicamba active ingredient

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Company Official:

James Wagner
Authorized Agent


Signature

Company Name: Sharda Cropchem Ltd.

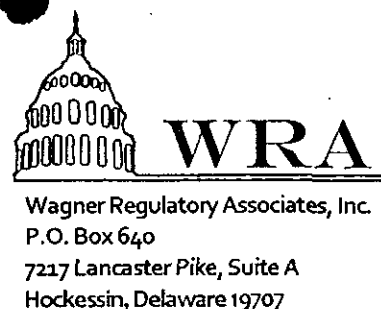
Company Contact:

James Wagner
Authorized Agent

(302) 635-7290
Phone

Submitted Electronically

December 22, 2016



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U.S. Environmental Protection Agency
Office of Pesticide Programs
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If you have any questions about this submission, please contact the undersigned at (302) 635-7290 or james@wagnerreg.com.

Respectfully submitted,

James Wagner
Agent for Sharda Cropchem, Ltd.

Enclosures

PRIA 3 – 21 Day Content Screen Review Worksheet

(EPA/OPP Use Only)

September 2012

21 Day Screen Start Date: 12-22-16

Experts In-Processing Signature: B.B. Date 1-17-17 Fee Paid: Yes ☒

Division management contacted on issues No ☐ Yes ☐ Date _____

EPA Reg. Number: <u>82633-20</u>		EPA Receipt Date: <u>12-22-16</u>				
Items for Review				Yes	No	N/A*
1	Application Form (EPA Form 8570-1) signed & complete including package type			X		
2	Confidential Statement of Formula all boxes completed, form signed, and dated (EPA Form 8570-4)			X		
	a) All <u>inerts</u> , including fragrances, approved for the proposed uses (see Footnote A) <u>No inerts to review</u>	yes	no			
3	Certification with Respect to Citation of Data (EPA Form 8570-34) completed and signed (N/A if 100% repack)			X		
	Certificate and data matrix consistent			X		
	If applicant is relying on data that are compensable, is the offer to pay statement included. (see Footnote B)	yes	no			
		X				
	If applicable, is there a letter of Authorization for exclusive use only.					
4	Formulator's Exemption Statement (EPA Form 8570-27) completed and signed (N/A if source is unregistered or applicant owns the technical)					X
	Data Matrix (EPA Form 8570-35) both internal and external copies (PR 98-5) completed and signed (N/A if 100% repack)			X		
5	a) Selective Method (Fee category experts use)	yes	no			
	b) Cite-All (Fee category experts use)	X				
	c) Applicant owns all data (Fee category experts use)					
6	5 Copies of <u>Label</u> (<u>Electronic labels on CD</u> are encouraged and guidance is available)					X
7	Is the data package consistent with PR Notice 86-5			X		
8	Notice of Filing included with petitions					X

9	If applicable for conventional applications, <u>reduced risk rationale</u>			
10	<u>Required Data</u> and/or data waivers. See Footnote C.			
	a) List study (or studies) not included with application			
<p>Comments:</p> <p>Documentation: <u>Pass</u> or Fail - All Required Forms Complete</p> <p>Inerts: <u>Pass</u> or Fail - Technical, [REDACTED] Impurities Only, No Inerts to Review</p> <p>PRN 11-03 <u>Pass</u> or Fail - MRID: 501376 • confidential contradiction pg 2-396 • illegible pg 331-332, 371-372, 374, 376, 378, 380, 382, 384 • contacted submitter 1/23/17 • issues corrected</p> <p>1/24/17</p> <p>Overall Status: <u>Pass</u> or Fail</p>				

* N/A – Not Applicable

Footnotes

A. During the 21 day initial content review, all CSFs will be reviewed to determine whether all inerts listed, including fragrances, are approved for the proposed uses or have an application pending with the Agency. If an unapproved inert with no application pending with the Agency is identified, the applicant must either 1) resolve the inert issue by, for example, removing the inert, substituting it with an approved inert, submitting documentation that EPA approved the inert for the proposed pesticidal uses, correcting mistakes on the CSF, etc. or 2) provide the data to support OPP approval of the inert or 3) withdraw the application. Removing or substituting an inert ingredient will require a new CSF and may require submission of data. All information, forms, data and documentation resolving the inert issue must have been received by the Agency or the application withdrawn within the 21 day period, otherwise, the Agency will reject the application as described below.

To successfully complete this aspect of the 21 day initial content screen, applicants are **strongly encouraged** to verify that all inert ingredients have been approved for the application's uses or have an application pending with the Agency **even if a product is currently registered** by consulting the [inert Web site](#) and if the inert is not approved nor has an application pending with the Agency, to **obtain the necessary inert approval prior to submitting an application to register a pesticide product containing that inert ingredient**. Some inert ingredients are no longer approved for food uses or certain types of uses. The name and/or CAS number on a CSF must match the name and CAS number on this web site. Simple typographical errors in the name or CAS number have resulted in processing delays.

If an inert is not listed on the inert ingredient web site and the applicant believes that the inert has been approved, the applicant should contact the Inert Ingredient Assessment Branch (IIAB) at inertsbranch@epa.gov and resolve the issue. Copies of the correspondence with IIAB resolving the issue should accompany the application. All new inerts except PIP inerts are reviewed by IIAB. The IIAB should also be contacted for any questions on what supporting data needs to be submitted for and the Agency's inert review process. Questions on PIP inerts should be directed to the [Chief of Microbial Pesticides Branch](#).

When a brand, trade, or proprietary name of an inert ingredient is listed on a CSF, additional information such as an alternate name of the inert, CAS number or other information must also be included to enable the Agency to determine if it has been approved. Each component of an inert mixture (including a fragrance) must be identified. In some cases, the supplier of the mixture or fragrance may need to provide this information to the Agency. Prior to the Agency's receipt of an application, applicants must arrange with a proprietary mixture or fragrance supplier to provide the component information to the Agency or promptly upon EPA's request. If the inert ingredients in a proprietary blend (including fragrances) cannot or are not identified or provided within the 21-day content review period, the Agency will reject the application.

During the 21 day content review, applicants should submit information to the individual identified by the Agency when the applicant is informed of an unapproved inert.

Unapproved Inerts Identified on CSFs

All applications except conventional new products and PIPs

Once an unapproved inert is identified on a CSF, the Agency will contact the applicant with the following options:

1. Correct the application by, for instance, correcting the inert's identity or CAS number, providing documentation that the inert has been approved, or removing the unapproved inert from the CSF or replacing it with one that is approved for the application's uses; or
2. Provide the required information necessary to identify an inert approval application that is pending with the Agency; or
3. Submit the information and data needed for the Agency to approve the unapproved inert. If this option is selected and implemented, the Agency may request an extension in the PRIA decision review timeframe to accommodate the inert review/approval process;
4. Withdraw the application (the Agency retains 25% of the full fee for the fee category estimated); or

If none of these options is selected and implemented by the applicant within the 21 day content review period, the Agency will reject the application and retain 25% of the full fee of the category identified.

Conventional New Product Applications

When the Registration Division identifies an unapproved inert on a CSF with an application for a new product that the applicant has not identified as requiring an inert approval (R300 or R301), it will contact the applicant with the following options:

1. Correct the application by, for instance, correcting the inert's identity or CAS number, providing documentation that the inert has been approved, or removing the unapproved inert from the CSF or replacing it with one that is approved for the application's uses; or
2. Submit the information and data needed for the Agency to approve the unapproved inert, including any required petition to establish or amend a tolerance or exemption from a tolerance. (This option may change the PRIA category for the application, which could require a longer decision review time and a larger fee. If additional fees are due, they must be received by the Agency within the 21 day content review period.)

3. Withdraw the application (the Agency retains 25% of the full fee for the fee category estimated); or

If none of the above options is selected and implemented during the 21-day content-review period, the Agency will reject the application and retain 25% of the appropriate fee for the new product-inert approval category.

PIP Applications

When the Biopesticide and Pollution Prevention Division identifies an unapproved inert on a PIP CSF and a request to approve the inert does not accompany the application, it will contact the applicant with the following options:

1. Correct the application by, for instance, correcting the spelling or name of the inert to that in 40 CFR 174, or providing documentation that the inert has been approved; or
2. Submit the information and data needed for the Agency to approve the unapproved inert. If an inert ingredient tolerance exemption petition is required, the petition must be received by the Agency and the B903 fee paid within the 21 day period. If this option is selected and implemented, the Agency will discuss harmonizing the timeframe for both actions.
3. Withdraw the application (the Agency retains 25% of the full fee for the fee category estimated); or

If none of the above options is selected and implemented during the 21 day content review period, the Agency will reject the application and retain 25% of the fee.

B. A policy on documentation of offers to pay is still being developed, however, for a me-too or fast track (similar/identical) new product, R300 or A530, an application without the necessary authorizations of offers to pay will be placed into either R301 or A531. The Agency recommends that authorizations of offers to pay be submitted with other PRIA applications to avoid delays in the Agency's decision.

C. Biopesticide applicants are advised to contact the Agency and discuss study waivers prior to submitting their application to the Agency. Documentation of such discussions should be submitted with the study waiver.

Varner, Stephanie

From: Kt Woodall <ktwoodall@wagnerreg.com>
Sent: Wednesday, January 25, 2017 8:07 AM
To: Varner, Stephanie
Cc: James Wagner
Subject: RE: Submission to EPA: SHARDA DICAMBA TECHNICAL (EPA Reg. No. 82633-20)
Attachments: 50137603 - 5-Batch.pdf

Good morning Stephanie – Please see the attached.

Thanks for all your help!

Katie Woodall

Wagner Regulatory Associates, Inc.

7217 Lancaster Pike, Suite A

Hockessin, DE 19707

KtWoodall@wagnerreg.com

katie@wagnerreg.com

From: Varner, Stephanie [<mailto:Varner.Stephanie@epa.gov>]
Sent: Tuesday, January 24, 2017 11:52 AM
To: Kt Woodall <ktwoodall@wagnerreg.com>
Subject: RE: Submission to EPA: SHARDA DICAMBA TECHNICAL (EPA Reg. No. 82633-20)

Hi Katie,
Yeah that'd be fine!
Thanks,
Stephnie

From: Kt Woodall [<mailto:ktwoodall@wagnerreg.com>]
Sent: Tuesday, January 24, 2017 11:50 AM
To: Varner, Stephanie <Varner.Stephanie@epa.gov>
Cc: James Wagner <jmw@wagnerreg.com>
Subject: RE: Submission to EPA: SHARDA DICAMBA TECHNICAL (EPA Reg. No. 82633-20)
Importance: High

Good afternoon Stephanie –

I have an email out to the client to see if they may have a clearer version. However, in the event that they do not, will "Best Available Copy" on each of those pages be sufficient?

Thanks for all your help!

Katie Woodall

Wagner Regulatory Associates, Inc.

7217 Lancaster Pike, Suite A

Hockessin, DE 19707

KtWoodall@wagnerreg.com

katie@wagnerreg.com

From: Varner, Stephanie [<mailto:Varner.Stephanie@epa.gov>]
Sent: Monday, January 23, 2017 10:57 AM
To: James Wagner <jmw@wagnerreg.com>
Subject: Submission to EPA: SHARDA DICAMBA TECHNICAL (EPA Reg. No. 82633-20)

Dear Mr. Wagner,

My name is Stephanie Varner, and I am a contractor with the EPA. I am contacting you in regards to your submissions in support of the product SHARDA DICAMBA TECHNICAL (EPA Reg. No. 82633-20). We have found a deficiency with the submissions that will need to be addressed:

1. There are issues with the submitted studies
 - o Study 501376-03 "Five Batch Analysis of Dicamba Technical" – the claim of no confidentiality is contradicted by confidential statements on pages 2-396; the following pages are illegible 331-332, 371-372, 374, 376, 378, 380, 382, 384.

Please send an updated version of the study to me.

Stephanie Varner

Contractor, US EPA
2777 S. Crystal Drive, S-4813
Arlington, VA 22202
(703) 347-0240
Email: varner.stephanie@epa.gov



UNITED STATES ENVIRONMENTAL PROTECTION AGENCY
WASHINGTON, D.C. 20460

January 13, 2017

OFFICE OF CHEMICAL SAFETY
AND POLLUTION PREVENTION

OPP Decision Number: D-525065
EPA File Symbol or Registration Number: 82633-20
Product Name: SHARDA DICAMBA TECHNICAL
EPA Receipt Date: 22-Dec-2016
EPA Company Number: 82633
Company Name: SHARDA CROPCHAM LIMITED

JAMES WAGNER
WAGNER REGULATORY ASSOCIATES, INC.
AGENT FOR SHARDA CROPCHAM LIMITED
PO BOX 640
HOCKESSIN, DE 19707-

SUBJECT: Receipt of Registration Amendment Subject to Registration Service Fee

Dear Registrant:

The Office of Pesticide Programs has received your amendment and certification of payment. If you submitted data with this application, the results of the PRN-2011-3 screen will be communicated separately. During the administrative screen, the Office of Pesticide Programs has determined that this Action is subject to a Pesticide Registration Service Fee as defined in the Pesticide Registration Improvement Act.

The Action has been identified as Action Code: R351

AMENDMENT; UNREGISTERED SOURCE OF ACTIVE INGREDIENT;

No additional payment is due at this time.

If you have any questions, please contact the Pesticide Registration Service Fee Ombudsman at (703) 308-9362.

Sincerely,

Front End Processing Staff
Information Technology & Resources Management Division

Fee for Service

7
{996779v~

This package includes the following

- ☐ New Registration
- ☒ Amendment

- ☐ Studies? ☐ Fee Waiver?
- ☐ volpay % Reduction: _____

for Division

- ☐ AD
- ☐ BPPD
- ☒ RD

Risk Mgr.

23

Receipt No.

S-

996779

EPA File Symbol/Reg. No.

82633-20

Pin-Punch Date:

12/22/2016

- ☐ This item is NOT subject to FFS action.

Action Code:

Requested:

R351

Granted:

R351

Amount Due: \$ 13226

Parent/Child Decisions:

☐ Inert Cleared for Intended Use

☐ Uncleared Inert in Product

Reviewer: L. Pabel

Date: 12/29/14

Remarks:

DOCUMENTUM

Submitted Electronically

December 22, 2016

Document Processing Desk (REGFEE)
ATTN: Kathryn Montague PM 23
Registration Division (7505P)
U.S. Environmental Protection Agency
Office of Pesticide Programs
One Potomac Yard
2777 South Crystal Drive
Arlington, Virginia 22202



Wagner Regulatory Associates, Inc.
P.O. Box 640
7217 Lancaster Pike, Suite A
Hockessin, Delaware 19707

Dear Ms. Montague,

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to add a new unregistered source of active ingredient (PRIA R351)**

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If you have any questions about this submission, please contact the undersigned at (302) 635-7290 or james@wagnerreg.com.

Respectfully submitted,

James Wagner
Agent for Sharda Cropchem, Ltd.

Enclosures

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Sharda Cropchem Ltd.
c/o Wagner Regulatory Associates
7217 Lancaster Pike, Suite A, PO Box 640
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Sharda Dicamba Technical - PRIA R351: Application for CSF Amendment – add new unregistered source of Dicamba active ingredient

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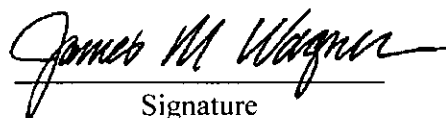
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Company Official:

James Wagner
Authorized Agent


Signature

Company Name: Sharda Cropchem Ltd.

Company Contact:

James Wagner
Authorized Agent

(302) 635-7290
Phone



United States
Environmental Protection Agency
Washington, DC 20460

Registration

OPP Identifier Number

Amendment

Other

Application for Pesticide - Section I

1. Company/Product Number 82633-20	2. EPA Product Manager Kathryn Montague	3. Proposed Classification <input checked="" type="checkbox"/> None <input type="checkbox"/> Restricted
4. Company/Product (Name) Sharda Cropchem Ltd./Sharda Dicamba Technical	PM# 23	
5. Name and Address of Applicant <i>(Include Zip Code)</i> Sharda Cropchem, Ltd. c/o Wagner Regulatory Associates, Inc. P.O. Box 640 Hockessin, DE 19707 <input type="checkbox"/> Check if this is a new address	6. Expedited Review. In accordance with FIFRA Section 3(c)(3) (b)(I), my product is similar or identical in composition and labeling to: EPA Reg. No. Product Name:	

Section - II

<input checked="checked" type="checkbox"/>	Amendment - Explain below.	<input type="checkbox"/>	Final printed labels in response to Agency letter dated _____
<input type="checkbox"/>	Resubmission in response to Agency letter dated _____	<input type="checkbox"/>	"Me Too" Application.
<input type="checkbox"/>	Notification - Explain below.	<input type="checkbox"/>	Other - Explain below.

Explanation: Use additional page(s) if necessary. (For Section I and Section II.)

PRIA R351 – Amendment to add a new unregistered source of Dicamba active ingredient.


Section - III

1. Material This Product Will Be Packaged In:

Child-Resistant Packaging <input type="checkbox"/> Yes* <input checked="" type="checkbox"/> No		Unit Packaging <input type="checkbox"/> Yes <input checked="" type="checkbox"/> No		Water Soluble Packaging <input type="checkbox"/> Yes <input checked="" type="checkbox"/> No		2. Type of Container <input type="checkbox"/> Metal <input checked="" type="checkbox"/> Plastic <input type="checkbox"/> Glass <input type="checkbox"/> Paper <input type="checkbox"/> Other (Specify) HDPE lined bags	
* Certification must be submitted		If "Yes" No. per Unit Packaging wgt. container		If "Yes" No. per Package wgt container			
3. Location of Net Contents Information <input checked="" type="checkbox"/> Label <input type="checkbox"/> Container			4. Size(s) Retail Container Bulk			5. Location of Label Directions <input checked="" type="checkbox"/> On Label <input type="checkbox"/> On Labeling accompanying product	
6. Manner in Which Label is Affixed to Product			<input type="checkbox"/> Lithograph <input checked="" type="checkbox"/> Paper glued <input type="checkbox"/> Stenciled		<input type="checkbox"/> Other ___adhesive backed label___		

Section - IV

1. Contact Point (Complete items directly below for identification of individual to be contacted, if necessary, to process this application.)

Name James Wagner	Title Agent for Sharda Cropchem, Ltd.	Telephone No. (Include Area Code) (302) 635-7290 (james@wagnerreg.com)
Certification I certify that the statements I have made on this form and all attachments thereto are true, accurate and complete. I acknowledge that any knowingly false or misleading statement may be punishable by fine or imprisonment or both under applicable law.		6. Date Application Received <div style="text-align: right;">(Stamped)</div>
2. Signature 	3. Title Agent for Sharda Cropchem, Ltd.	
4. Typed Name James Wagner	5. Date December 22, 2016	



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1200 Pennsylvania Avenue, N.W.
WASHINGTON, D.C. 20460

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Certification with Respect to Citation of Data

Applicant's/Registrant's Name, Address, and Telephone Number Sharda Cropchem Ltd., Domnic Holm, 29th Rd, Bandra (West) Mumbai, India 400050	EPA Registration Number/File Symbol 82633-20
Active Ingredient(s) and/or representative test compound(s) Dicamba	Date December 22, 2016
General Use Pattern(s) (list all those claimed for this product using 40 CFR Part 158) Terrestrial Food Use, Terrestrial Non-Food	Product Name Sharda Dicamba Technical

NOTE: If your product is a 100% repackaging of another purchased EPA-registered product labeled for all the same uses on your label, you do not need to submit this form. You must submit the Formulator's Exemption Statement (EPA Form 8570-27).

☐ I am responding to a Data-Call-In Notice, and have included with this form a list of companies sent offers of compensation (the Data Matrix form should be used for this purpose).

SECTION I: METHOD OF DATA SUPPORT (Check one method only)

<input type="checkbox"/> I am using the cite-all method of support, and have included with this form a list of companies sent offers of compensation (the Data Matrix form should be used for this purpose).	<input checked="" type="checkbox"/> I am using the selective method of support (or cite-all option under the selective method), and have included with this form a completed list of data requirements (the Data Matrix form must be used).
--	---

SECTION II: GENERAL OFFER TO PAY

[Required if using the cite-all method or when using the cite-all option under the selective method to satisfy one or more data requirements]

☒ I hereby offer and agree to pay compensation, to other persons, with regard to the approval of this application, to the extent required by FIFRA.

SECTION III: CERTIFICATION

I certify that this application for registration, this form for reregistration, or this Data-Call-In response is supported by all data submitted or cited in the application for registration, the form for reregistration, or the Data-Call-In response. In addition, if the cite-all option or cite-all option under the selective method is indicated in Section I, this application is supported by all data in the Agency's files that (1) concern the properties or effects of this product or an identical or substantially similar product, or one or more of the ingredients in this product; and (2) is a type of data that would be required to be submitted under the data requirements in effect on the date of approval of this application if the application sought the initial registration of a product of identical or similar composition and uses.

I certify that for each exclusive use study cited in support of this registration or reregistration, that I am the original data submitter or that I have obtained the written permission of the original data submitter to cite that study.

I certify that for each study cited in support of this registration or reregistration that is not an exclusive use study, either: (a) I am the original data submitter; (b) I have obtained the permission of the original data submitter to use the study in support of this application; (c) all periods of eligibility for compensation have expired for the study; (d) the study is in the public literature; or (e) I have notified in writing the company that submitted the study and have offered (i) to pay compensation to the extent required by sections 3(c)(1)(F) and/or 3(c)(2)(B) of FIFRA; and (ii) to commence negotiations to determine the amount and terms of compensation, if any, to be paid for the use of the study.

I certify that in all instances where an offer of compensation is required, copies of all offers to pay compensation and evidence of their delivery in accordance with sections 3(c)(1)(F) and/or 3(c)(2)(B) of FIFRA are available and will be submitted to the Agency upon request. Should I fail to produce such evidence to the Agency upon request, I understand that the Agency may initiate action to deny, cancel or suspend the registration of my product in conformity with FIFRA.

I certify that the statements I have made on this form and all attachments to it are true, accurate, and complete. I acknowledge that any knowingly false or misleading statement may be punishable by fine or imprisonment or both under applicable law.

Signature <i>James M. Wagner</i>	Date 12/22/2016	Typed or Printed Name and Title James Wagner, Agent (Tel: 302-635-7290)
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WASHINGTON, D.C. 20460

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DATA MATRIX

Date: December 22, 2016	EPA Reg No./ File Symbol: 82633-20	Page 1 of 3
Applicant's/Registrant's Name and Address: Sharda Cropchem, Ltd. Domnic Holm, 29 th Road Bandra (West), Mumbai, India 400050	Product: Sharda Dicamba Technical	
Ingredient: Dicamba		

Guideline Reference Number	Guideline Study Name	MRID Number	Submitter	Status	Note
PRODUCT SPECIFIC					
830.1550, 830.1600, 830.1620, 830.1750	Product identity, composition/Description of materials Used to Produce the Product/Description of Production Process	50094101 50137601	Sharda Cropchem Ltd.	Own	
830.1670	Discussion of Formation of Impurities	50137602	Sharda Cropchem Ltd.	Own	
830.1700	Preliminary Analysis	50094102 50094103 50094104 50137603	Sharda Cropchem Ltd.	Own	
830.1750	Certification of Limits	50094101	Sharda Cropchem Ltd.	Own	
830.1800	Enforcement Analytical Method	50094102 50137603	Sharda Cropchem Ltd.	Own	
830.6302	Color	49085104	Sharda Cropchem Ltd.	Own	
830.6303	Odor	49085104	Sharda Cropchem Ltd.	Own	
830.6304	Physical State	49085104	Sharda Cropchem Ltd.	Own	
830.6313	Stability to Normal & Elevated Temperatures	49085105	Sharda Cropchem Ltd.	Own	
830.6314	Oxidation/Reduction	50094105	Sharda Cropchem Ltd.	Own	
830.6315	Flammability	49085107	Sharda Cropchem Ltd.	Own	
830.6316	Explosibility	50094105	Sharda Cropchem Ltd.	Own	
830.6317	Accelerated Storage Stability	49085105 49085106	Sharda Cropchem Ltd.	Own	
830.6319	Miscibility	50094105	Sharda Cropchem Ltd.	Own	
830.6320	Corrosion Characteristics	49085105 49085106	Sharda Cropchem Ltd.	Own	

Signature 	Name and Title James Wagner, Agent for Sharda Cropchem, Ltd.	Date Dec. 22, 2016
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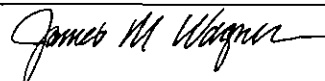
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Applicant's/Registrant's Name and Address: Sharda Cropchem, Ltd. Domnic Holm, 29 th Road Bandra (West), Mumbai, India 400050	Product: Sharda Dicamba Technical	
Ingredient: Dicamba		

Guideline Reference Number	Guideline Study Name	MRID Number	Submitter	Status	Note
830.6321	Dielectric Breakdown Voltage	50094105	Sharda Cropchem Ltd.	Own	
830.7000	pH	49085108	Sharda Cropchem Ltd.	Own	
830.7050	UV/Visible Light Absorption	50094105	Sharda Cropchem Ltd.	Own	
830.7100	Viscosity	50094105	Sharda Cropchem Ltd.	Own	
830.7200	Melting Point	50094105	Sharda Cropchem Ltd.	Own	
830.7220	Boiling Point	50094105	Sharda Cropchem Ltd.	Own	
830.7300	Relative Density	49085109	Sharda Cropchem Ltd.	Own	
830.7370	Dissociation Constants in Water	49085110	Sharda Cropchem Ltd.	Own	
830.7520	Particle Size	50094105	Sharda Cropchem Ltd.	Own	
830.7550	Octanol/Water Partition Coefficient	49085111	Sharda Cropchem Ltd.	Own	
830.7840	Solubility in Organic Solvents	49085112	Sharda Cropchem Ltd.	Own	
830.7840	Water Solubility	49085112	Sharda Cropchem Ltd.	Own	
830.7950	Vapor Pressure	50094105	Sharda Cropchem Ltd.	Own	
870.1100	Acute Oral Toxicity -- rat	49085113	Sharda Cropchem Ltd.	Own	
870.1200	Acute Dermal Toxicity -- rat	49085114	Sharda Cropchem Ltd.	Own	
870.1300	Acute Inhalation Toxicity -- rat	49085115	Sharda Cropchem Ltd.	Own	
870.2400	Eye Irritation	49085116	Sharda Cropchem Ltd.	Own	
870.2500	Skin Irritation	49085117	Sharda Cropchem Ltd.	Own	
870.2600	Skin Sensitization	49085118	Sharda Cropchem Ltd.	Own	
GENERIC DATA	GENERIC DATA	Cite All	Syngenta Crop Prot, Greensboro, NC Nufarm Americas, Morrisville, NC The Scotts Co, Marysville, OH BASF Corp, Research Triangle Park, NC	Pay	

Signature 	Name and Title James Wagner, Agent for Sharda Cropchem, Ltd.	Date Dec. 22, 2016
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DATA MATRIX

Date: December 22, 2016	EPA Reg No./ File Symbol: 82633-20	Page 3 of 3
Applicant's/Registrant's Name and Address: Sharda Cropchem, Ltd. Domnic Holm, 29 th Road Bandra (West), Mumbai, India 400050	Product: Sharda Dicamba Technical	
Ingredient: Dicamba		

Guideline Reference Number	Guideline Study Name	MRID Number	Submitter	Status	Note
Generic Data	Generic Data	Cite All	Bayer CropSc, Research Triangle Park, NC	Pay	
			E.I. DuPont, Wilmington, DE		
			Bayer Envir, Research Triangle Park, NC		
			Monsanto Co, Washington, DC		
			Lebanon Seaboard Corp, Lebanon, PA		
			Winfield Solutions, St. Paul, MN		
			PBI/Gordon Corp, Kansas City, MO		
			Chemsico, St. Louis, MO		
			Loveland Products, Greeley, CO		
			Nufarm Ltd, Morrisville, NC		
			Albaugh, Valdosta, GA		
			Control Solutions, Pasadena, TX		
			Dow Agros, Indianapolis, IN		
			Spray Drift Task Fce, Washington, DC		
			Petro-Canada Lubricants, Wash, DC		
			Gharda USA, Newtown, PA		
			Outdoor Res Exp Task, Washington, DC		
			Ag Reentry Task Force, Washington, DC		
			Bayer Adv, Research Triangle Park, NC		
			FIFRA End Spec Task, Lakewood, WA		
			Resid Exp Jnt Ven, Washington, DC		
			Ag Handler Exp Task Fce, Macon, MO		
			Mey Corp, Chapel Hill, NC		

Signature:	Name and Title James Wagner, Agent for Sharda Cropchem, Ltd.	Date Dec. 22, 2016
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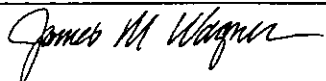
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Applicant's/Registrant's Name and Address: Sharda Cropchem, Ltd. Domnic Holm, 29 th Road Bandra (West), Mumbai, India 400050	Product: Sharda Dicamba Technical	
Ingredient: Dicamba		

Guideline Reference Number	Guideline Study Name	MRID Number	Submitter	Status	Note
			Libertas Now, Wilmington, DE		
			Tacoma Ag, Gig Harbor, WA		

Footnotes:

Signature 	Name and Title James Wagner, Agent for Sharda Cropchem, Ltd.	Date Dec. 22, 2016
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Applicant's/Registrant's Name and Address: Sharda Cropchem, Ltd. Domnic Holm, 29 th Road Bandra (West), Mumbai, India 400050	Product: Sharda Dicamba Technical	
Ingredient: Dicamba		

Guideline Reference Number	Guideline Study Name	MRID Number	Submitter	Status	Note
			Sharda Cropchem Ltd.	Own	
			Sharda Cropchem Ltd.	Own	
			Sharda Cropchem Ltd.	Own	
			Sharda Cropchem Ltd.	Own	
			Sharda Cropchem Ltd.	Own	
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			Sharda Cropchem Ltd.	Own	
			Sharda Cropchem Ltd.	Own	
			Sharda Cropchem Ltd.	Own	

Signature 	Name and Title James Wagner, Agent for Sharda Cropchem, Ltd.	Date Dec. 22, 2016
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Applicant's/Registrant's Name and Address: Sharda Cropchem, Ltd. Domnic Holm, 29 th Road Bandra (West), Mumbai, India 400050	Product: Sharda Dicamba Technical	
Ingredient: Dicamba		

Guideline Reference Number	Guideline Study Name	MRID Number	Submitter	Status	Note
			Sharda Cropchem Ltd.	Own	
			Sharda Cropchem Ltd.	Own	
			Sharda Cropchem Ltd.	Own	
			Sharda Cropchem Ltd.	Own	
			Sharda Cropchem Ltd.	Own	
			Sharda Cropchem Ltd.	Own	
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			Sharda Cropchem Ltd.	Own	
			Sharda Cropchem Ltd.	Own	
			Sharda Cropchem Ltd.	Own	
			Sharda Cropchem Ltd.	Own	
			Syngenta Crop Prot, Greensboro, NC	Pay	
			Nufarm Americas, Morrisville, NC		
			The Scotts Co, Marysville, OH		
			BASF Corp, Research Triangle Park, NC		

Signature 	Name and Title James Wagner, Agent for Sharda Cropchem, Ltd.	Date Dec. 22, 2016
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Applicant's/Registrant's Name and Address: Sharda Cropchem, Ltd. Domnic Holm, 29 th Road Bandra (West), Mumbai, India 400050	Product: Sharda Dicamba Technical	
Ingredient: Dicamba		

Guideline Reference Number	Guideline Study Name	MRID Number	Submitter	Status	Note
			Bayer CropSc, Research Triangle Park, NC	Pay	
			E.I. DuPont, Wilmington, DE		
			Bayer Envir, Research Triangle Park, NC		
			Monsanto Co, Washington, DC		
			Lebanon Seaboard Corp, Lebanon, PA		
			Winfield Solutions, St. Paul, MN		
			PBI/Gordon Corp, Kansas City, MO		
			Chemsico, St. Louis, MO		
			Loveland Products, Greeley, CO		
			Nufarm Ltd, Morrisville, NC		
			Albaugh, Valdosta, GA		
			Control Solutions, Pasadena, TX		
			Dow Agros, Indianapolis, IN		
			Spray Drift Task Fce, Washington, DC		
			Petro-Canada Lubricants, Wash, DC		
			Gharda USA, Newtown, PA		
			Outdoor Res Exp Task, Washington, DC		
			Ag Reentry Task Force, Washington, DC		
			Bayer Adv, Research Triangle Park, NC		
			FIFRA End Spec Task, Lakewood, WA		
			Resid Exp Jnt Ven, Washington, DC		
			Ag Handler Exp Task Fce, Macon, MO		
			Mey Corp, Chapel Hill, NC		

Signature 	Name and Title James Wagner, Agent for Sharda Cropchem, Ltd.	Date Dec. 22, 2016
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Applicant's/Registrant's Name and Address: Sharda Cropchem, Ltd. Domnic Holm, 29 th Road Bandra (West), Mumbai, India 400050	Product: Sharda Dicamba Technical	
Ingredient: Dicamba		

Guideline Reference Number	Guideline Study Name	MRID Number	Submitter	Status	Note
			Libertas Now, Wilmington, DE		
			Tacoma Ag, Gig Harbor, WA		

Footnotes:

Signature 	Name and Title James Wagner, Agent for Sharda Cropchem, Ltd.	Date Dec. 22, 2016
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Receipt

Your payment is complete

Pay.gov Tracking ID: 25VMK7KF
Agency Tracking ID: 75152142910
Form Name: Pesticide Registration Improvement Act - Prepayment
Application Name: PRIA Service Fees

Payment Information

Payment Type: Debit or credit card
Payment Amount: \$13,226.00
Transaction Date: 12/22/2016 01:23:16 PM EST
Payment Date: 12/22/2016
Registration Number: 82633-20
Company Name: Sharda Cropchem Ltd
Company Number: 82633
Action Code: R351

Account Information

Cardholder Name: Cheryl R. Wagner
Card Type: American Express
Card Number: *****2008

Email Confirmation Receipt

Confirmation Receipts have been emailed to:
cheryl@wagnerreg.com

DOCUMENTUM



Wagner Regulatory Associates, Inc.
P.O. Box 640
7217 Lancaster Pike, Suite A
Hockessin, Delaware 19707

Submitted Electronically

October 28, 2016

Document Processing Desk (AMEND)
ATTN: Kathryn Montague PM 23
Registration Division (7505P)
U.S. Environmental Protection Agency
Office of Pesticide Programs
One Potomac Yard
2777 South Crystal Drive
Arlington, Virginia 22202

Dear Ms. Montague,

**Subject: Sharda Dicamba Technical – EPA Registration No. 82633-20 – CSF Amendment
Addition of Alternate Unregistered Source**

Wagner Regulatory Associates, Inc., as agent for Sharda Cropchem Ltd., respectfully submits an addition of alternate unregistered source for the subject product containing Dicamba (PC Code 029801). In support of this request, the following documents have been uploaded to the CDX portal with this submission:

- Letter from Sharda Cropchem, Ltd, appointing Wagner Regulatory Associates, Inc. as its agent
- Application for Pesticide Amendment (8570-1)
- Alternate Confidential Statement of Formula (8570-4)
- Certification with Respect to Citation of Data (8570-34)
- Data Transmittal document
- Data Matrix (internal and public)
- Submission of Studies as reflected in the data transmittal document
- PRIA fee receipt reflecting payment in the amount of \$13,226 for R351

If you have any questions about this submission, please contact the undersigned at (302) 510-0039 or anna@wagnerreg.com.

Respectfully submitted,

Anna Armstrong
Agent for Sharda Cropchem, Ltd.

Enclosures

DATA TRANSMITTAL DOCUMENT**1. Name and Address of Submitter**

Sharda Cropchem Ltd.
 c/o Wagner Regulatory Associates
 7217 Lancaster Pike, Suite A, PO Box 640
 Hockessin, DE 19707

2. Regulatory Action In Support Of Which This Package Is Submitted

Application for CSF Amendment – Add Alternate Unregistered Source
Sharda Dicamba Technical

3. Transmittal Date

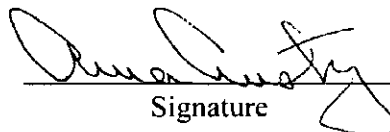
October 28, 2016

4. List of Submitted Studies

50094101	Dicamba Technical – Group A Product Identity and Composition, Description of Materials, Description of Manufacturing Process, Discussion of Formation of Impurities, Toxicity of Impurities and Certified Limits; OPPTS Guidelines: 830.1550, 830.1600, 830.1650, 830.1670, 830.1700, 830.1750
50094102	Physical and Chemical Characteristics Dicamba Technical, Study No. EPP00136, OPPTS Guidelines: 830.1700, 830.1800
50094103	Amendment Report of Dicamba Technical, OPPTS Guidelines: 830.1700, 830.1800
50094104	Dioxins Report, Dicamba Technical, Study No. 01.19750.01.001, OPPTS Guidelines: 830.1700, 830.1800
50094105	Dicamba Technical – Product Chemistry – Group B: Literature Citations and Request for Waiver for Certain Physical/Chemical Properties Data; OPPTS Guidelines: 830.6314, 830.6316, 830.6319, 830.6321, 830.7100, 830.7200, 830.7220, 830.7520, 830.7950

Company Official:

Anna Armstrong
 Authorized Agent


 Signature

Company Name: Sharda Cropchem Ltd.

Company Contact:

Anna Armstrong
 Authorized Agent

(302) 510-0039
 Phone

This is a reproduction of EPA Form 8570-1 (Rev. 8-94) Previous editions are obsolete.



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WASHINGTON, D.C. 20460

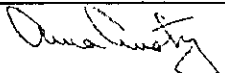
Form Approved OMB No. 2070-0060

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DATA MATRIX

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Applicant's/Registrant's Name and Address: Sharda Cropchem, Ltd. Domnic Holm, 29 th Road Bandra (West), Mumbai, India 400050	Product: Sharda Dicamba Technical	
Ingredient: Dicamba		

Guideline Reference Number	Guideline Study Name	MRID Number	Submitter	Status	Note
PRODUCT SPECIFIC					
830.1550, 830.1600, 830.1620, 830.1670, 830.1750	Product identity, composition/Description of materials Used to Produce the Product/Description of Production Process/Discussion of Formation of Impurities	50094101	Sharda Cropchem Ltd.	Own	
830.1700	Preliminary Analysis	50094102 50094103 50094104	Sharda Cropchem Ltd.	Own	
830.1750	Certification of Limits	50094101	Sharda Cropchem Ltd.	Own	
830.1800	Enforcement Analytical Method	50094102	Sharda Cropchem Ltd.	Own	
830.6302	Color	49085104	Sharda Cropchem Ltd.	Own	
830.6303	Odor	49085104	Sharda Cropchem Ltd.	Own	
830.6304	Physical State	49085104	Sharda Cropchem Ltd.	Own	
830.6313	Stability to Normal & Elevated Temperatures	49085105	Sharda Cropchem Ltd.	Own	
830.6314	Oxidation/Reduction	50094105	Sharda Cropchem Ltd.	Own	
830.6315	Flammability	49085107	Sharda Cropchem Ltd.	Own	
830.6316	Explosibility	50094105	Sharda Cropchem Ltd.	Own	
830.6317	Accelerated Storage Stability	49085105 49085106	Sharda Cropchem Ltd.	Own	
830.6319	Miscibility	50094105	Sharda Cropchem Ltd.	Own	
830.6320	Corrosion Characteristics	49085105 49085106	Sharda Cropchem Ltd.	Own	
830.6321	Dielectric Breakdown Voltage	50094105	Sharda Cropchem Ltd.	Own	
830.7000	pH	49085108	Sharda Cropchem Ltd.	Own	

Signature 	Name and Title Anna Armstrong, Agent for Sharda Cropchem, Ltd.	Date Oct. 28, 2016
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UNITED STATES ENVIRONMENTAL PROTECTION AGENCY
401 M Street, S.W.
WASHINGTON, D.C. 20460

Form Approved OMB No. 2070-0060

Paperwork Reduction Act Notice: The public reporting burden for this collection of information is estimated to average 0.25 hours per response for registration activities and 0.25 hours per response for reregistration and special review activities, including time for reading the instruction and completing the necessary forms. Send comments regarding the burden estimate or any other aspect of this collection of information, including suggestions for reducing the burden to: Director, OPPE Information Management Division (2137), U.S. Environmental Protection Agency, 401 M Street, S.W., Washington DC 20460. Do not send the form to this address.

DATA MATRIX

Date: 10/28/2016	EPA Reg No./ File Symbol: 82633-20	Page 2 of 3
Applicant's/Registrant's Name and Address: Sharda Cropchem, Ltd. Domnic Holm, 29 th Road Bandra (West), Mumbai, India 400050	Product: Sharda Dicamba Technical	
Ingredient: Dicamba		

Guideline Reference Number	Guideline Study Name	MRID Number	Submitter	Status	Note
830.7050	UV/Visible Light Absorption	50094105	Sharda Cropchem Ltd.	Own	
830.7100	Viscosity	50094105	Sharda Cropchem Ltd.	Own	
830.7200	Melting Point	50094105	Sharda Cropchem Ltd.	Own	
830.7220	Boiling Point	50094105	Sharda Cropchem Ltd.	Own	
830.7300	Relative Density	49085109	Sharda Cropchem Ltd.	Own	
830.7370	Dissociation Constants in Water	49085110	Sharda Cropchem Ltd.	Own	
830.7520	Particle Size	50094105	Sharda Cropchem Ltd.	Own	
830.7550	Octanol/Water Partition Coefficient	49085111	Sharda Cropchem Ltd.	Own	
830.7840	Solubility in Organic Solvents	49085112	Sharda Cropchem Ltd.	Own	
830.7840	Water Solubility	49085112	Sharda Cropchem Ltd.	Own	
830.7950	Vapor Pressure	50094105	Sharda Cropchem Ltd.	Own	
870.1100	Acute Oral Toxicity – rat	49085113	Sharda Cropchem Ltd.	Own	
870.1200	Acute Dermal Toxicity – rat	49085114	Sharda Cropchem Ltd.	Own	
870.1300	Acute Inhalation Toxicity – rat	49085115	Sharda Cropchem Ltd.	Own	
870.2400	Eye Irritation	49085116	Sharda Cropchem Ltd.	Own	
870.2500	Skin Irritation	49085117	Sharda Cropchem Ltd.	Own	
870.2600	Skin Sensitization	49085118	Sharda Cropchem Ltd.	Own	
GENERIC DATA	GENERIC DATA	Cite All	Syngenta Crop Prot. Greensboro, NC Nufarm Americas, Morrisville, NC The Scotts Co, Marysville, OH BASF Corp, Research Triangle Park, NC Bayer CropSc, Research Triangle Park, NC E.I. DuPont, Wilmington, DE	Pay	

Signature 	Name and Title Anna Armstrong, Agent for Sharda Cropchem, Ltd.	Date Oct. 28, 2016
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Date: 10/28/2016	EPA Reg No./ File Symbol: 82633-20	Page 3 of 3
Applicant's/Registrant's Name and Address: Sharda Cropchem, Ltd. Domnic Holm, 29 th Road Bandra (West), Mumbai, India 400050	Product: Sharda Dicamba Technical	
Ingredient: Dicamba		

Guideline Reference Number	Guideline Study Name	MRID Number	Submitter	Status	Note
Generic Data	Generic Data	Cite All	Bayer Envir, Research Triangle Park, NC	Pay	
			Monsanto Co. Washington, DC		
			Lebanon Seaboard Corp, Lebanon, PA		
			Winfield Solutions, St. Paul, MN		
			PBI/Gordon Corp, Kansas City, MO		
			Chemsico, St. Louis, MO		
			Loveland Products, Greeley, CO		
			Nufarm Ltd, Morrisville, NC		
			Albaugh, Valdosta, GA		
			Control Solutions, Pasadena, TX		
			Dow Agros, Indianapolis, IN		
			Spray Drift Task Fce, Washington, DC		
			Petro-Canada Lubricants, Wash, DC		
			Gharda USA, Newtown, PA		
			Outdoor Res Exp Task, Washington, DC		
			Ag Reentry Task Force, Washington, DC		
			Bayer Adv, Research Triangle Park, NC		
			FIFRA End Spec Task, Lakewood, WA		
			Resid Exp Jnt Ven, Washington, DC		
			Ag Handler Exp Task Fce, Macon, MO		
			Mey Corp, Chapel Hill, NC		
			Libertas Now, Wilmington, DE		
			Tacoma Ag, Gig Harbor, WA		

Footnotes:

Signature 	Name and Title Anna Armstrong, Agent for Sharda Cropchem, Ltd.	Date Oct. 28, 2016
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Applicant's/Registrant's Name and Address: Sharda Cropchem, Ltd. Domnic Holm, 29 th Road Bandra (West), Mumbai, India 400050	Product: Sharda Dicamba Technical	
Ingredient: Dicamba		

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PRODUCT SPECIFIC					
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830.1700	Preliminary Analysis	50094102 50094103 50094104	Sharda Cropchem Ltd.	Own	
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830.6302	Color	49085104	Sharda Cropchem Ltd.	Own	
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830.6313	Stability to Normal & Elevated Temperatures	49085105	Sharda Cropchem Ltd.	Own	
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Signature 	Name and Title Anna Armstrong, Agent for Sharda Cropchem, Ltd.	Date Oct. 28, 2016
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830.7370	Dissociation Constants in Water	49085110	Sharda Cropchem Ltd.	Own	
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830.7550	Octanol/Water Partition Coefficient	49085111	Sharda Cropchem Ltd.	Own	
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870.2400	Eye Irritation	49085116	Sharda Cropchem Ltd.	Own	
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870.2600	Skin Sensitization	49085118	Sharda Cropchem Ltd.	Own	
GENERIC DATA	GENERIC DATA	Cite All	Syngenta Crop Prot. Greensboro, NC	Pay	
			Nufarm Americas. Morrisville, NC		
			The Scotts Co. Marysville, OH		
			BASF Corp. Research Triangle Park, NC		
			Bayer CropSc. Research Triangle Park, NC		
			E.I. DuPont, Wilmington, DE		

Signature 	Name and Title Anna Armstrong, Agent for Sharda Cropchem, Ltd.	Date Oct. 28, 2016
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401 M Street, S.W.
WASHINGTON, D.C. 20460

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Ingredient: Dicamba		

Guideline Reference Number	Guideline Study Name	MRID Number	Submitter	Status	Note
Generic Data	Generic Data	Cite All	Bayer Envir, Research Triangle Park, NC	Pay	
			Monsanto Co, Washington, DC		
			Lebanon Seaboard Corp, Lebanon, PA		
			Winfield Solutions, St. Paul, MN		
			PBI/Gordon Corp, Kansas City, MO		
			Chemsico, St. Louis, MO		
			Loveland Products, Greeley, CO		
			Nufarm Ltd, Morrisville, NC		
			Albaugh, Valdosta, GA		
			Control Solutions, Pasadena, TX		
			Dow Agros, Indianapolis, IN		
			Spray Drift Task Fce, Washington, DC		
			Petro-Canada Lubricants, Wash, DC		
			Gharda USA, Newtown, PA		
			Outdoor Res Exp Task, Washington, DC		
			Ag Reentry Task Force, Washington, DC		
			Bayer Adv, Research Triangle Park, NC		
			FIFRA End Spec Task, Lakewood, WA		
			Resid Exp Int Ven, Washington, DC		
			Ag Handler Exp Task Fce, Macon, MO		
			Mey Corp, Chapel Hill, NC		
			Libertas Now, Wilmington, DE		
			Tacoma Ag, Gig Harbor, WA		

Footnotes:

Signature 	Name and Title Anna Armstrong, Agent for Sharda Cropchem, Ltd.	Date Oct. 28, 2016
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UNITED STATES ENVIRONMENTAL PROTECTION AGENCY
1200 Pennsylvania Avenue, N.W.
WASHINGTON, D.C. 20460

Paperwork Reduction Act Notice: The public reporting burden for this collection of information is estimated to average 1.25 hours per response for registration and 0.25 hours per response for reregistration and special review activities, including time for reading the instructions and completing the necessary forms. Send comments regarding burden estimate or any other aspect of this collection of information, including suggestions for reducing the burden to: Director, Collection Strategies Division (2822T), U.S. Environmental Protection Agency, 1200 Pennsylvania Avenue, N.W., Washington, DC 20460. Do not send the completed form to this address.

Certification with Respect to Citation of Data

Applicant's/Registrant's Name, Address, and Telephone Number Sharda Cropchem Ltd., Domnic Holm, 29th Rd, Bandra (West) Mumbai, India 400050	EPA Registration Number/File Symbol 82633-20
Active Ingredient(s) and/or representative test compound(s) Dicamba	Date October 28, 2016
General Use Pattern(s) (list all those claimed for this product using 40 CFR Part 158) Terrestrial Food Use, Terrestrial Non-Food	Product Name Sharda Dicamba Technical

NOTE: If your product is a 100% repackaging of another purchased EPA-registered product labeled for all the same uses on your label, you do not need to submit this form. You must submit the Formulator's Exemption Statement (EPA Form 8570-27).

☐ I am responding to a Data-Call-In Notice, and have included with this form a list of companies sent offers of compensation (the Data Matrix form should be used for this purpose).

SECTION I: METHOD OF DATA SUPPORT (Check one method only)

<input type="checkbox"/> I am using the cite-all method of support, and have included with this form a list of companies sent offers of compensation (the Data Matrix form should be used for this purpose).	<input checked="" type="checkbox"/> I am using the selective method of support (or cite-all option under the selective method), and have included with this form a completed list of data requirements (the Data Matrix form must be used).
--	---

SECTION II: GENERAL OFFER TO PAY

[Required if using the cite-all method or when using the cite-all option under the selective method to satisfy one or more data requirements]

☒ I hereby offer and agree to pay compensation, to other persons, with regard to the approval of this application, to the extent required by FIFRA.

SECTION III: CERTIFICATION

I certify that this application for registration, this form for reregistration, or this Data-Call-In response is supported by all data submitted or cited in the application for registration, the form for reregistration, or the Data-Call-In response. In addition, if the cite-all option or cite-all option under the selective method is indicated in Section I, this application is supported by all data in the Agency's files that (1) concern the properties or effects of this product or an identical or substantially similar product, or one or more of the ingredients in this product; and (2) is a type of data that would be required to be submitted under the data requirements in effect on the date of approval of this application if the application sought the initial registration of a product of identical or similar composition and uses.

I certify that for each exclusive use study cited in support of this registration or reregistration, that I am the original data submitter or that I have obtained the written permission of the original data submitter to cite that study.

I certify that for each study cited in support of this registration or reregistration that is not an exclusive use study, either: (a) I am the original data submitter; (b) I have obtained the permission of the original data submitter to use the study in support of this application; (c) all periods of eligibility for compensation have expired for the study; (d) the study is in the public literature; or (e) I have notified in writing the company that submitted the study and have offered (i) to pay compensation to the extent required by sections 3(c)(1)(F) and/or 3(c)(2)(B) of FIFRA; and (ii) to commence negotiations to determine the amount and terms of compensation, if any, to be paid for the use of the study.

I certify that in all instances where an offer of compensation is required, copies of all offers to pay compensation and evidence of their delivery in accordance with sections 3(c)(1)(F) and/or 3(c)(2)(B) of FIFRA are available and will be submitted to the Agency upon request. Should I fail to produce such evidence to the Agency upon request, I understand that the Agency may initiate action to deny, cancel or suspend the registration of my product in conformity with FIFRA.

I certify that the statements I have made on this form and all attachments to it are true, accurate, and complete. I acknowledge that any knowingly false or misleading statement may be punishable by fine or imprisonment or both under applicable law.

Signature 	Date October 28, 2016	Typed or Printed Name and Title Anna Armstrong, Agent (Tel: 302-510-0039)
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From: notification@pay.gov
To: Anna Armstrong
Subject: Pay.gov Payment Confirmation: PRIA Service Fees
Date: Thursday, October 27, 2016 10:47:29 AM

Your payment has been submitted to Pay.gov and the details are below. If you have any questions regarding this payment, please contact Michael Yanchulis at (703) 347-0237 or yanchulis.michael@epa.gov.

Application Name: PRIA Service Fees
Pay.gov Tracking ID: 25UM65JS
Agency Tracking ID: 75118114598
Transaction Type: Sale
Transaction Date: 10/27/2016 10:47:24 AM EDT

Account Holder Name: Cheryl R. Wagner

Transaction Amount: \$13,226.00
Card Type: AmericanExpress
Card Number: *****2008

Registration Number: 82633-20
Company Name: Sharda CropChem
Company Number: 82633
Action Code: R351

THIS IS AN AUTOMATED MESSAGE. PLEASE DO NOT REPLY.

Sharda Cropchem Limited

(Formerly known as Sharda Worldwide Exports Pvt. Ltd.)

Tel. : +91 22 66782800

Fax : +91 22 66782828 / 66782808

E-mail: shardain@vsnl.com

Regd. Office : Domnic Holm, 29th Road, Bandra (W), Mumbai - 400050, India.



ISO 9001: 2008 Reg. No: 690257



February 13, 2014

To: Whom it May Concern

Re: Sharda Cropchem Ltd

This letter serves as notification that Sharda Cropchem Ltd has appointed Wagner Regulatory Associates, Inc. (WRA, Inc.) to serve as the Agent on our company's behalf regarding state and/or federal regulatory matters as determined by Sharda Cropchem Ltd. The following employees of Wagner Regulatory Associates, Inc. are authorized to act on our behalf:

James Wagner
Email: james@wagnerreg.com
Phone: 302-635-7290

Cheryl Wagner
Email: cheryl@wagnerreg.com
Phone: 302-635-7289

Carrie Nolan
Email: carrie@wagnerreg.com
Phone: 302-635-7632

Barbarette Young-Henry
Email: barbarette@wagnerreg.com
Phone: 302-635-7279

Kt Woodall
Email: ktwoodall@wagnerreg.com
Phone: 302-635-7281

Correspondence can be addressed to any of the above employees at:

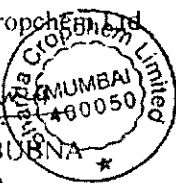
Wagner Regulatory Associates
P. O. Box 640
Hockessin, DE 19707-0640

Thank you for your time and assistance. Please feel free to contact Wagner Regulatory Associates should you have any questions.

Respectfully submitted,

For Sharda Cropchem Ltd

ASHISH R. BUDNA
(DIRECTOR)



cc: WRA, Inc.

